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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,839	03/30/2004	Theoharis C. Theoharides	2003133.125US11	3048
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WILMERHALE/BOSTON 60 STATE STREET BOSTON, MA 02109			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 04/17/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/811,839	Applicant(s) THEOHARIDES, THEOHARIS C.	
	Examiner Casey S. Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/31/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination/Amendment/Remarks filed 11/17/2008 and IDS filed 12/31/2008.

Claims 1-44 have been cancelled. Claims 45-63 are newly added. Thus, claims 45-63 are currently pending.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and/or 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant claims the instant application is a CIP of PCT/US02/00476 which is a CIP of USPA 09/771,669 which is a CIP of 09/056,707.

The disclosure of the prior-filed application, Application No. '476, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The corresponding published

Art Unit: 1615

document for '476 is WO 2002/060393. '393 does not have support for the limitations "pelvic inflammatory condition", "folic acid" or "a polyunsaturated fatty acid" of instant claim 45.

Accordingly, Applicants are not afforded priority to said application '476 or its parent applications '669 and '707. Therefore, without evidence to the contrary, the filing date of 3/30/2004 is deemed the priority date of the instant application.

WITHDRAWN REJECTIONS

Applicant's amendment renders the objection of claim 39 and rejection(s) of claims 42, 43 and 44 under 35 USC 112, 1st and 2nd paragraphs moot. Specifically, said claims were cancelled. Thus, said objection and rejections have been withdrawn.

MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 6/17/2008:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 45-48 and 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsberg et al. (US 2006/0210551 A1).

Lindsberg teaches compositions comprising a mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent (Abstract). Lindsberg teaches that a preferable mast cell degranulation-blocking agent is a histamine-1 receptor antagonist including hydroxyzine (paragraphs [0036]-[0037]). Lindsberg further teaches other agents that inhibit mast cell secretion and proliferation including flavonoids such as quercetin optionally in combination with chondroitin sulfate (paragraph [0038]). Lindsberg also teaches that the mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent is administered in a therapeutically effective amount, typically about 0.05-100 mg per kg body weight of the patient (paragraph [0040]). Lindsberg also teaches that unit dosage forms preferably contain about 0.1 to about 1000 mg of active compound (paragraph [0044]).

A person of ordinary skill in the art would have been motivated to combine chondroitin sulfate, hydroxyzine and/or quercetin and because Linsdberg teaches all of the agents to be used for the same purpose (i.e., art recognized equivalents). A

Art Unit: 1615

practitioner would have reasonably expected a composition effective in blocking mast cell granulation.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose The idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846,850,205 USPQ 1069, 1072 (CCPA 1980).

Therefore, in Lindsberg, it would have been prima facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to have combined chondroitin sulfate, hydroxyzine and/or quercetin in order to form a new composition effective in blocking mast cell granulation.

It is noted that claims 45-59 are composition claims and as such any intended use recitation such as "for treating a pelvic inflammatory condition" in claim 45 does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

In light of rejection under 35 USC 112, 2nd paragraph and giving the claims their broadest most reasonable interpretation, Lindsberg also reads on the limitations of claims 52-55.

Thus, the teachings of Lindsberg render the instant claims obvious.

Response to Arguments

Applicant's arguments with respect to the rejection under 103 over Lindsberg have been fully considered but they are not persuasive.

Applicant argues that Lindsberg can not be prior art because the instant application claims priority to 1998 and Lindsberg's earliest effective filing date is 2003 (page 7 of Remarks).

In response, it is respectfully submitted that Applicant is not entitled priority to 1998 as discussed above in the Priority section of the Office Action. The filing date of 3/30/2004 is deemed the priority date of the instant application. Thus, contrary to Applicant's assertions, Lindsberg applies as prior art at this time.

It is noted that the rejection has been modified to reflect Applicant's amendment.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

NEW REJECTIONS

In light of Applicant's amendments, the following rejections have been newly added:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-63 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes a species of the instantly claimed "pelvic inflammatory condition" at paragraph [034], that is, endometriosis, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by pelvic inflammatory conditions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 and 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Said claims depend from claim 45. Claims 45 is drawn to a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

Claim 48 recites the limitation, "wherein the flavonoid is quercetin, myricetin, genistein, or rutin". It is unclear whether the claim is further limiting the flavonoid genus or whether the claims is intending to limit the Markush group of claim 45 to only said flavonoid species. If the latter, it is suggested that Applicant amend the claim to include the limitation, "wherein the at least one ingredient selected from the group consisting of is a flavonoid, wherein said flavonoid is...".

Similarly, claims 51-59 contain the same lack of clarity.

The Examiner is giving said claims their broadest most reasonable interpretation. For example, claim 48 is being interpreted by the Examiner to mean "a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, quercetin, myricetin, genistein, rutin, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

Clarification/correction is respectfully requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-48, 51-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Florio (WO 97/21434).

Florio teaches nutritional supplements for treating arthritis comprising gamma linolenic acid, the polyunsaturated fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), the sulfated proteoglycans chondroitin sulfate, N-acetyl glucosamine sulfate and glucosamine sulfate, and manganese aspartate (abstract). Florio further exemplifies amounts of said ingredients including 250mg of glucosamine, 100 mg of chondroitin sulfate, 400 mg of EPA and 300 mg of DHA (page 13, lines 21, 22 and 25).

In light of rejection under 35 USC 112, 2nd paragraph and giving the claims their broadest most reasonable interpretation, Florio also reads on the limitations of claims 48, 51 and 53-59.

Thus, the disclosures of Florio render the instant claims anticipated.

Claims 45-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Theoharides (WO 02/060393 A2).

Theoharides teaches proteoglycan compositions for treatments of inflammatory conditions comprising a sulfated proteoglycan such as chondroitin sulfate and one or more of a hexosamine sulfate such as D-glucosamine sulfate, a flavone such as quercetin, an refined kernel olive oil that increases absorption, S-adenosylmethionine (SAM), a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine and a polyamine (abstract). Theoharides teaches other suitable proteoglycans including keratin sulfate, dermatan sulfate and sodium hyaluronate (page 6, lines 1-2), other suitable flavones including myricetin, genistein and kaempferol (page 6, lines 10-11), suitable histamine-1 receptor antagonists including hydroxyzine, azelastine, azatadine and cyproheptadine (page 7, lines 1-3). Theoharides further teaches preferred concentrations of the proteoglycan, hexosamine sulfate and flavones to be 10-3000 mg, SAM to be 3-1000 mg and unrefined kernel olive oil to be 900-1200 mg (page 7, lines 21-28). Example 10 exemplifies the particular combination of chondroitin sulfate, quercetin and hydroxyzine and Example 14 exemplifies the particular combination of chondroitin sulfate, myricetin and hydroxyzine.

Thus, the disclosures of Theoharides render the instant claims anticipated.

Art Unit: 1615

Claims 60-63 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Crea (US 2004/0039066 A1).

Crea teaches treating inflammatory conditions including inflammatory pelvic disease (paragraph [0060]) and administration of a composition comprising one or more components selected from the group consisting of glucosamine sulfate, chondroitin sulfate, sea cucumber extract, hydrolyzed shark cartilage, collagen II, and methylsulfonylmethane (paragraph [0053]). It is noted that the teaching of “one or more” and finite group of disclosed components reads on the combination of glucosamine sulfate and chondroitin sulfate.

In light of rejection under 35 USC 112, 2nd paragraph and giving the claims their broadest most reasonable interpretation, Crea also reads on the limitations of claims 61-63.

Thus, the disclosures of Crea render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides (WO 02/060393 A2).

Theoharides teaches the elements discussed above. Specifically, Example 10 teaches a composition comprising 50 mg of chondroitin sulfate, 400 mg of quercetin and 50 mg of hydroxyzine and Example 14 teaches a composition comprising 500 mg of myricetin, 200 mg of chondroitin sulfate and optionally, hydroxyzine.

With regards to instant claim 57, Theoharides is silent to the amount of quercetin being 50-300 mg and with regards to claim 59, Theoharides is silent to myricetin and hydroxyzine each in the amount of 50-300 mg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include said ingredients in the amounts claimed with a reasonable expectation of success because the prior art teaches broad ranges inclusive of the claimed amounts as well as utilize the claimed ingredients in the claimed amounts in other formulations. Thus, in light of the teachings of Theoharides it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the compositions by way of routine experimentation.

The teachings of Theoharides render the instant claims obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 1615

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 15-27 of U.S. Patent No. 6,984,667 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter in the claims of the patent '667 anticipates the subject matter of the claims in the instant application.

For instance, claim 1 of '667 is drawn to a composition comprising a non-bovine proteoglycan and unrefined kernel olive oil, and one or more of D-hexosamine sulfate, a flavonoid, S-adenosylmethionine, and a histamine-1-receptor antagonist, in an appropriate excipient or vehicle.

Claim 45 of the instant application is drawn to a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

Claims 45-50, 53, 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,115,278 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter in the claims of the patent '667 anticipates the subject matter of the claims in the instant application.

For instance, claim 1 of '278 is drawn to a composition comprising, in mg, chondroitin sulfate, 25-75; rutin, 25-75; quercetin, 50-150; S-adenosylmethionine, 150-250; folic acid, 0.17-0.37; fish oil polyunsaturated fatty acids, 150-200; microfiltered olive kernel extract, 200-300; bitter willow extract, 10-50; suspension agents, 50-70

Claim 45 of the instant application is drawn to a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615